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EXAMINER

ARIANI, KADE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Art Unit: 1651

Attachment to the Advisory Action:

Applicant arguments with respect to the rejection of claims 1, 2, and 4-11, and 13-31 under 35 U.S.C. 103(a), filed on 5/18/2010 is considered but is not found persuasive.

Applicant argues that the cited references do not provide any guidance or experimental data to show that FAOD can be used in a pretreatment to degrade and remove free amino acid that is glycosylated. These arguments have been considered but are not found persuasive because as mentioned in the Office Action of 02/18/2010, Yoshida et al. teach a fructosyl amino acid oxidase (FAOD) which is active towards a glycosylated amino acid and that the enzyme did not use glycosylated proteins directly as its substrate.

Moreover, Fry et al. teach the formation of free amino acids that are glycosylated in parenteral nutritional solutions used for intravenous feeding (reaction products between glucose and free amino acids in glucose and amino acid solutions). Fry et al. further teach these products can enter circulation of the patients infused with these solutions during intravenous feeding (p.1636 2<sup>nd</sup> column 3<sup>rd</sup> paragraph). Therefore, a person of ordinary skill in the art at the time the invention was made would have recognized the presence of free amino acids in the blood sample of patients infused with these solutions, also a person of ordinary skill in the art at the time the invention was made would have recognized that any glycosylated amino acids (unrelated to the glycosylated protein to be measured) in the blood sample would interfere with the measurement of the glycosylated protein.

Moreover, as long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor. See *In re Beattie*, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992); *In re Kronig*, 539 F.2d 1300, 190 USPQ 425 (CCPA 1976) and *In re Wilder*, 429 F.2d 447, 166 USPQ 545 (CCPA 1970). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Applicant argues that Komori, Ishimaru, Montellano are silent as to the combined use of a tetrazolium compound and sodium azide. This argument has been considered but is not found persuasive. Because claim 1 (lines14-15) reads "the redox reaction is conducted in the presence of a tetrazolium compound and sodium azide" thus there is no limitation in claim 1 to the combined use of a of a tetrazolium compound and sodium azide. Moreover, Ishimaru et al. teach hydrogen peroxide generated by the FAOD (FAOD reaction product) can be removed by using catalase, and Montellano et al. teach using 0.15-0.6 mM sodium azide to inhibit catalase. Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to add sodium azide in the method as taught by Komori et al. to inhibit catalase and to stop the redox reaction of catalase.

/Leon B Lankford/

Primary Examiner, Art Unit 1651